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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Request For Waiver of Repeat Fish Full Life Cycle Study With
Fenamidone (MRID 47332201)

FROM: Colleen Flaherty, Biologist *Colleen M. Flaherty* 08 May 2008
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THRU: Tom Bailey, Ph.D. *Tom A. Bailey*
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In 2004, Bayer CropScience LP submitted a fish full life cycle study in which fenamidone fungicide significantly reduced the number of eggs/female and the number of spawns/female at the lowest level tested, 8.6 $\mu\text{g/L}$ (MRID 46418602). Thus, a definitive NOAEC was not determined in the study (i.e., NOAEC < 8.6 $\mu\text{g/L}$). In order to reduce uncertainty in the aquatic risk assessment for fenamidone, the EFED recommended that another fish full life cycle study (§72-5) be performed to determine the chronic reproductive NOAEC in freshwater fish.

Bayer CropScience LP has recently submitted a waiver request for a repeat fish full life cycle study with fenamidone, citing "unusually high levels of egg production in the two control replicates." The submission includes a re-analysis of the study using contemporary control data. The EFED has considered this submission and rejects this waiver request because treatment means can only be assessed relative to the controls that were run concurrently with the study.¹ The EFED recommends that another fish full life

¹Urban, D.J. 1998. U.S. EPA, Office of Pesticide Programs, Environmental Fate and Effects Division. Memorandum: Reply to rapid response request re: mallard reproduction study - evaluation of certain results [Ref. Fax dated 12/29/98].

cycle study be performed to reduce the uncertainty regarding the chronic risk of fenamidone to fish. EFED recommends that test treatments below 8.6 µg/L be included in the range of concentrations and encourages the use of more replicates per treatment level (*i.e.*, 4 replicates as suggested in the guideline), which would increase the statistical power of all analyses and minimize any variability associated effects.